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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,648	11/13/2000	Dean M. Ponzi	37646/KMO/W112	7874

23363 7590 08/17/2006

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EXAMINER
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MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.	Applicant(s)	
09/711,648	PONZI ET AL.	
Examiner	Art Unit	
Elizabeth R. MacNeill	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20, 23-35, 39 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 23-35, 39 and 42-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

This action is in response to amendments submitted on 30 June 2006.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-15, 17-20, 23-25, 27, 28, 30-35, 39 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by ABELE (US #5,403,311).

Regarding claim 1, Abele teaches "An injection catheter comprising: a catheter body (28) comprising a flexible tubing (30) having proximal and distal ends and at least one lumen (not labeled, Col 5 lines 47-65) there through; a tip section (e.g. 52) having a longitudinal axis and comprising a flexible tubing having proximal and distal ends, wherein the proximal end of the tip section is mounted at the distal end of the catheter body (Fig 1, Fig 6); a needle control handle (17) at the proximal end of the catheter body; an injection needle (24) extending through the tip section, catheter body, and needle control handle and having a proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that upon suitable manipulation of the needle control handle the distal end of the injection needle can extend distally beyond the distal end of the tip section in a direction along the longitudinal axis of the tip section to penetrate tissue generally facing a distal face of the tip section (Fig 1); an electrode lead wire

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having a first end electrically connected to the injection needle (26) and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy (16)." See also Col 3, lines 25-52, and Col 4 lines 19-29.

Regarding claims 9 and 11, Abele teaches the limitations of claim 1 above, with the substitution and/or addition of an electrode mounted on the injection needle being electrically isolated for the injection needle. (Col 8 lines 50-Col 9 line 5).

Regarding claim 23, the claim recites the same limitations as claim 1 without explicitly defining the tip section. Examiner takes the proximal end of the catheter to be equivalent to the tip section of claim 1; therefore claim 23 is rejected under Abele.

Regarding claims 2,3,24, and 25, the electrode can be mounted at the distal or proximal end of the injection needle (52,56)

Regarding claims 5,6,27 and 28, Examiner takes the protective tube to be the cross-braided stainless steel filaments 30.

Regarding claims 7,14,19, and 46, Abele teaches the use of at least one additional electrode (Fig 10, 72 and 74)

Regarding claim 8, Abele teaches that the tip of the needle can be an electrode (Col 6 line 15)

Regarding claim 10, Abele teaches the use of a ring electrode (e.g. 26, Col 5 line 51)

Regarding the method claims 12,13,15,17,18,20,30-35,44,45, and 47, Abele describes various potential methods of use, disclosing all the of the claimed methods. See "Summary of the Invention" and "Description of Preferred Embodiments."

Regarding claims 42 and 43, Adele teaches the use a penetration monitoring electrode "Adjustment of the length of axial extension of the probe is effective to determine the depth of penetration and thereby the depth of coagulation of tissue" (Col 4 lines 65-68)

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adele.

Claim 16 specifies that the type of drug injected by the needle is selected from the group angiogenesis activators, angiogenesis inhibitors, and antiarrhythmic drugs." Adele teaches the limitations of claims 12 and 1, but only specifies the use of a "vasoconstrictor, sclerotic, topical anesthetic, or heat responsive drug." Because Adele's catheter and the disclosed invention are both designed to be used to abate tissue in the heart, the selection of one drug over another is a matter of obvious design choice.

5. Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adele as applied to claims 1 and 23 above, and further in view of COOSMAN (US #4,966,597).

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Adele teaches the limitations of a catheter for introduction into cardiac tissues, but does not teach the use of a pair of copper and constantan wires used as a thermocouple probe.

Cossman teaches the use of a thermocouple composed of copper and constantan wires (elements 1 and 5) in a cardiac catheter (Fig 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the electrode thermocouple probe of Cossman with the cardiac catheter of Adele in order to facilitate "true surface temperature recording with fast response" (Cossman Abstract)

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1-20,23-28,30-35,39 and 42-47 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

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Machell  
11/08/2006*

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